

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

UNITED STATES OF AMERICA, ex)	Case No.: 5:15CV611
rel. KEVIN MANIERI,)	
)	
Plaintiff-Relator,)	JUDGE LIOI
)	
v.)	
)	
AVANIR PHARMACEUTICALS, INC.,)	
)	<u>JOINT STIPULATION OF</u>
)	<u>PARTIAL DISMISSAL</u>
Defendant.)	
)	

Pursuant to Rule 41(a) of the Federal Rules of Civil Procedure, the United States of America, having intervened in this qui tam action brought pursuant to the False Claims Act, 31 U.S.C. § 3729, *et seq.* (“FCA”), and the Relator hereby notify the Court of the voluntary partial dismissal of this action, consistent with the terms of the settlement agreement dated September 25, 2019 (the “Settlement Agreement”), as set forth below.

The United States, the Relator, and defendant Avanir Pharmaceuticals, Inc. (“Avanir”) (collectively, the “Parties”) have executed a Settlement Agreement in full compromise and settlement of certain of the United States’ claims, as well as the claims that the Relator has asserted on behalf of the United States, against Avanir. In accordance with, and subject to the

terms of the Settlement Agreement, the United States and the Relator are voluntarily dismissing, with prejudice, the claims asserted by the Relator in this action, on behalf of the United States, against Avanir that are based on the Covered Conduct as defined in Recitals, Paragraph E of the Settlement Agreement, which specifically provides as follows:

E. The United States contends that it has certain civil claims against Avanir based on the following conduct between October 29, 2010 and December 31, 2016 (hereinafter referred to as the “Covered Conduct”):

1. Avanir provided remuneration in the form of money, honoraria, travel, and food to certain physicians and other health care professionals (HCPs) to induce those certain HCPs to write prescriptions for Nuedexta. One form of remuneration included Avanir’s payment to certain HCPs to give talks (commonly known as “speaker’s programs”) about Nuedexta based on the willingness of the HCPs to prescribe Nuedexta.

One example of such remuneration involved a physician who gave 55 speaker programs for Avanir from July 2015 through February 2016. These 55 programs, however, only had 42 unique attendees, the vast majority of whom were not physicians, according to the sign-in sheets for the events. The sign-in sheets, however, also contain signatures that the Avanir sales representative either manufactured or obtained under false pretenses. Restaurants adjusted the number of attendees on the final bill to make it appear as though there were more attendees for these speaker program events than were actually present, at the request of the Avanir sales representative. These events were primarily social, with no educational value. This physician was one of Avanir’s top prescribers; in addition to the remuneration for the speaker programs, he received other inducements from certain Avanir employees, such as dinner and, on at least one occasion, liquor.

2. Avanir implemented a strategy to market Nuedexta to HCPs treating patients in long-term care (LTC) facilities for uses other than PBA. Non-PBA uses are not FDA approved and are also not medically accepted indications as defined by the statutes and regulations governing the Federal health care programs. Specifically, to counter the objection by certain HCPs that they had few, if any, patients that exhibited signs of PBA in their facilities, Avanir instructed sales representatives to provide false and misleading information that PBA patients could be exhibiting a wide variety of “behaviors” such as crying without tears, moaning, or making other inarticulate sounds, without sufficiently distinguishing patients who have dementia without PBA from patients who have dementia with PBA.

In addition, Avanir sought to capitalize on efforts by the Centers for Medicare and Medicaid Services (CMS) to reduce the use of anti-psychotics on dementia patients in LTC facilities, based in part on CMS’s concern that anti-psychotics can be and have

been used as a form of chemical restraint for residents. In announcing a reduction initiative in 2012, CMS stated that it was “emphasizing non-pharmacological alternatives for nursing home residents,” and, as one component of the initiative, CMS began publishing data on the use of anti-psychotics in nursing homes. Considering this initiative “an opportunity,” Avanir sent a marketing communication to HCPs “express[ing] its support” for the CMS initiative, which stated that “[d]ementia patients may be on an anti-psychotic to treat the symptoms of [PBA]” and emphasized that Nuedexta “is not categorized as an anti-psychotic medication.” In one example, an Avanir sales representative asked to speak to staff at a facility about PBA and Nuedexta, presenting Nuedexta as an “alternate solution” to psychotropics for nursing home residents. Similarly, in 2015, when CMS took further steps to reduce anti-psychotic use, Avanir instructed its sales force to “leverage” the opportunity in LTC facilities to initiate discussions regarding anti-psychotic use and how Nuedexta could be used to reduce a LTC facility’s reliance on antipsychotics even though Avanir’s own studies demonstrated that the actual population of patients with PBA is limited; those studies posited that the prevalence of PBA across the six most commonly associated underlying neurologic conditions is estimated to be approximately ten percent. This strategy worked, and Nuedexta utilization in LTC facilities increased.

In one example, an Avanir employee reported that one doctor, who was also a paid speaker for Nuedexta, had “entire units” of patients on Nuedexta at the LTC facility where he worked, which contained a large number of dementia patients with behavioral issues. And while another doctor, a geriatrician, who also worked in the same LTC facility routinely discontinued Nuedexta for patients, the doctor paid by Avanir “constantly re-initiat[ed]” the treatment.

As a result of the foregoing alleged conduct, the United States alleges that Avanir knowingly caused false and/or fraudulent claims to be submitted to the United States and Medicare, Medicaid, TRICARE, FEHBP, and purchases of the drug by the Department of Veterans Affairs.

In addition, the Relator is voluntarily dismissing, with prejudice to the Relator and without prejudice to the United States, the remaining claims asserted by the Relator in this action on behalf of the United States against Avanir, in which claims the United States has declined to intervene. Pursuant to the False Claims Act, 31 U.S.C. § 3730(b)(1), the United States hereby consents to the Relator’s voluntary dismissal of that portion of the action, provided that such dismissal is without prejudice to the United States.

Relator is not dismissing his claims against Avanir for wrongful termination under 31 U.S.C. § 3730(h), or his claims regarding attorney's fees, costs, and expenses under 31 U.S.C. § 3730(d).

Defendant has not filed an answer or responsive pleading to the Complaint.

A proposed order has been submitted for the Court's consideration.

Respectfully submitted,

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